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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,259	10/31/2003	Beth P. Nguyen	PROTEO.P08CI	7361

7590 06/11/2007

PROTEOTECH, INC.
12040 115TH AVE. NE
KIRKLAND, WA 98034

EXAMINER	
KOLKER, DANIEL E	
ART UNIT	**PAPER NUMBER**
1649	

MAIL DATE	DELIVERY MODE
06/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,259	NGUYEN ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *11-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/21/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendments filed 23 March 2007 and remarks filed 12 February 2007 have been entered. Claims 1 – 32 are pending.

Election/Restrictions

2. Claims 11 – 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11 April 2006.

3. Claims 1 – 10 are under examination.

Information Disclosure Statement

4. The IDS filed 21 March 2007 has been considered. Note reference B has been crossed out by the examiner as it is duplicative; the reference was cited by the examiner in the previous office action.

Withdrawn Rejections and Objections

5. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejection under 35 USC 112 second paragraph is withdrawn as applicant has amended the claims to recite the generic name of the product, as opposed to the trademark.

Maintained Rejections and Objections

Priority

6. The effective filing date for all claims under examination is 1 November 2002 for the reasons previously made of record. In the remarks filed 12 February 2007 applicant accepted the examiner's determination of priority for the purposes of applying prior art (see p. 4, second paragraph). Applicant traversed the priority determination "for the reason that should Applicant wish to later file continuation or divisional applications claiming earlier filed subject matter, they would be deprived of the benefit of the earlier filing date." While this is an explanation for applicant's traversal, it is noted that applicant did not point out any legal or factual mistakes in the examiner's analysis of priority. The effective filing date remains 1 November 2002.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Castillo (1997. Journal of Neurochemistry 69:2452-2465, cited in office action mailed 20 November 2006).

This rejection stands for the reasons of record. Briefly, Castillo teaches immobilizing perlecan (also known as sulfated glycosaminoglycan heparan sulfate, recited in claim 7) on microtiter wells, which is on point to claim 1 part (a) and claim 6, and adding A-beta 1-40, which is on point to claim 1 part(b). Thus the reference anticipates claims 1, 6, and 7. Claims 2 – 5 are anticipated as the Castillo reference teaches the ranges recited in these claims.

Applicant argues that the rejection should be withdrawn as the reference does not teach all elements of the invention claimed. Applicant did not traverse the examiner's determination that steps (a) and (b) of claim 1 are taught by the reference, nor did applicant traverse the examiner's determination that the ranges of claims 2 – 5 are taught by the reference, nor did applicant traverse the examiner's determination that the relevant items recited in claims 6 – 7 are taught by the reference. Rather, applicant argues that Castillo "examines molecular binding affinities" but "does not teach how to bring the molecules into plaque formation".

Applicant's arguments have been fully considered but they are not persuasive. It appears applicant is arguing that the prior art reference is not enabling. Independent claim 1 requires the following starting materials:

a) a selected SGAG immobilized on a selected medium

b) dissolved low fibrillar A-beta 1-40.

Both of these are clearly provided by Castillo. Independent claim 1 is a method which requires only a single step, namely that the A-beta be added to the SGAG. This step of "adding" is taught by Castillo. While the reference does not explicitly teach "how to bring the molecules into plaque formation" as applicant argues, this step is not claimed. As the prior art reference teaches the same starting materials and the same method steps, it anticipates the claimed

method. There are no elements recited in independent claim 1 which do not appear in the reference by Castillo. Thus the prior art reference anticipates the methods of claims 1 – 7.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 – 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Castillo (1997. Journal of Neurochemistry 69:2452-2465) in view of Cross (1989. Journal of Tissue Culture Methods 12:57-59).

This rejection stands for the reasons of record. Applicant traverses on the following grounds:

a) the examiner has failed to provide "some suggestion of the desirability of doing what the inventor has done" (remarks, p. 4), and

b) Castillo does not teach a method of inducing plaque formation and thus cannot serve as a primary reference in a rejection under 35 USC § 103.

Applicant's arguments have been fully considered but they are not persuasive. With respect to (a) above, the examiner specifically pointed out the advantages the 96-well Teflon (PTFE fluoropolymer) coated partitioned block taught by Cross would have in the method of Castillo. These advantages were cited in the paragraph spanning pp. 4 – 5 of the previous office action and include use of a format convenient for researchers due the presence of the standard 96-well arrangement and the ability of the Teflon block to be re-sterilized, thereby decreasing waste and cost. Clearly, the examiner did in fact provide a motivation to combine the teachings of the references. With respect to (b) above, the reasons why Castillo does in fact anticipate claims 1 – 7 are set forth in the rejection under 35 USC § 102 above and for the sake of brevity will not be reiterated herein.

9. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castillo in view of Cross as applied to claims 1 – 8 above, and further in view of Roach (U.S. Patent 3,494,201, issued 10 February 1970).

This rejection stands for the reasons of record. Applicant traverses on the following grounds:

a) the examiner has failed to provide "some suggestion of the desirability of doing what the inventor has done" (remarks, p. 4), and

b) Castillo does not teach a method of inducing plaque formation and thus cannot serve as a primary reference in a rejection under 35 USC § 103.

Applicant's arguments have been fully considered but they are not persuasive. With respect to (a) above, the examiner specifically indicated on p. 5 of the previous office action that the motivation to use a bubbling technique as recited in claims 9 – 10 would be to ensure that the entire volume of the A-beta solution is displaced from the pipet that delivers it. With respect to (b) above, the reasons why Castillo does in fact anticipate claims 1 – 7 are set forth in the rejection under 35 USC § 102 above and for the sake of brevity will not be reiterated herein.

Double Patenting

10. Claims 1 – 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 6 – 9, 14 – 15, and 19 – 21 of U.S. Patent No. 7,148,001. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the parent application do not require that the GAGs be immobilized. However this very minor modification would be obvious to one of ordinary skill in the art as immobilizing the GAGs would allow for rapid separation of the A-beta fibrils from the GAGs after the fibrils had formed.

This rejection stands for the reasons of record. Applicant did not traverse the rejection but rather stated that a terminal disclaimer may be filed in the future. No such disclaimer has been filed, so the rejection stands for the reasons of record. In the previous office action, this rejection was a provisional rejection as the application (10/007779) had been allowed but had not yet issued as a patent. The '779 application has now issued as the '001 patent.

Conclusion

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker, Ph.D.
May 29, 2007

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER